

## **REMARKS**

Applicant's counsel thanks the Examiner for the careful consideration given the application. The specification has been amended as requested by the Examiner. A Terminal Disclaimer is enclosed herewith to obviate the double patenting rejection; please make the Terminal Disclaimer of record in this case.

The claims have been rejected as obvious over Iijima et al. and other references. However, upon more careful consideration, it is clear that claims 1-59 are not obvious over Iijima et al. or Iijima et al. in view of Richardson et al. or in view of Brommelsiek et al.

The Examiner, at the start of point 5, argues that the invention is "a composition of matter comprising particles with a core of choline chloride as a dry crystalline powder and a coating of carnauba wax and a hydrophobic substance (selected from vegetable oils). Feed pellets, premix for feed and mash containing the composition are also claimed."

The Applicant argues that a composition of matter wherein there is an internal layer of vegetable oil and an outer layer of carnauba wax, not the composition of matter as described above, is the invention claimed. This double-layered composition is advantageous. It is advantageous because it substantially lowers and minimizes the degradation of rumen by-pass quality as explained at page 9-11 of the Application and demonstrated experimentally in Tables 1-5 against particles containing only carnauba wax or hydrogenated vegetable oil layers. As shown in Tables 1-5, this effect is synergic as it is substantially improved (ie. lowered percentage of degradation) compared to a layer consisting of a mix of the carnauba wax and hydrogenated vegetable oil (ref. Control 3 as described at page 24-25 of the Application).

The comparison between the particle as described by the invention and the one described by the Examiner at point 5 is thus experimentally shown and demonstrates that the degradation of rumen by-pass quality is minimised in the particle according to the present invention.

The Examiner then cites the pertinent sections of Iijima et al which describe a granular composition comprising containing choline for a ruminant. Said granules "are overcoated

with a thin film by adding 20 to 40 parts, preferably 20 to 30 parts by weight, of a molten mixture,... of a hydrophobic overcoating agent and a solubility agent and a solubility modifier" (Col. 6, line 67 to Co. 7, line 6). Hydrophobic agents such as vegetable oils and carnauba wax are disclosed as binders and overcoating agents for granules.

The Applicant argues that said texts do not teach or incentivise the PHOSITA (Person Having Ordinary Skill In The Art) to produce the double layered particles of choline chloride with the associated advantages as mentioned above.

The Examiner then agrees that there is no specific teaching of the double layered coating according to the invention. Thus the applicant argues that for the double-layered particle according to claim 1 to be obvious, the PHOSITA needs to be suggested by the prior art that the surprising advantages are possible from this specific particle.

The Applicant cannot see any such suggestion cited.

The Examiner points out that Iijima et al. teaches that an over-coating agent should have a melting point 5 degrees lower than the binder material and can be similar material or the same. Thus the Examiner argues that following the teachings of Iijima et al, the PHOSITA can reach, and is suggested to reach the double layer coated particle according to claim 1, wherein the inner layer is hydrogenated vegetable oil and the outer layer is carnauba wax.

The Applicant argues that Iijima does not teach this possible combination because Iijima teaches at column 3 that the hydrophobic agents like hydrogenated vegetable oil or carnauba wax are applied as a binder and not a layer. This is a notable difference for the following reasons:

- Iijima does not require the binder material to form a layer, unlike the inner layer formed by the current Application. The difference, as taught by Iijima et al, between binder and layer is seen by the difference in the process taught for forming the binder (ref. Example 1 first paragraph and col.5 and 6 of Iijima et al.) respect to the formation of the over-coating layer (ref. Example 1 second paragraph and col. 7, second paragraph of Iijima et al.) This is also proven by the difference with the methods that are described for encapsulation of the core particles by layers in the present Application at page 5 of the present Application. Methods cited therein, such as fluidised-bed technology are not applicable to material designated as binder, but only as encapsulating and therefore layering material.

- The objective of the present Application is to have a more efficient delivery system of choline chloride for ruminant animals by decreasing "the degeneration of rumen-by-pass quality", 1<sup>st</sup> para. of page 9. The core consisting of mainly choline chloride crystals as defined in claim 1 is advantageous because it allows high concentration of choline chloride (ref. p.15, second paragraph of the Application). This would not be possible with a binder of hydrogenated vegetable oil or carnauba wax as taught in Iijima et al., and thus the advantage is not obvious to the PHOSITA.
- The current Application also features the use of a binder. It prefers a high concentration of choline chloride crystals, and thus teaches the use of binders such as stearates (ref. p. 16, second paragraph of the Application), not the hydrogenated vegetable oils as cited by the Examiner
- The PHOSITA, in considering Iijima et al., would consider to treat the term binder in its classical pharmaceutical sense and not as a layer. Please find enclosed a citation from a Chemical Dictionary, wherein the term is clearly juxtaposed to that of the layer.

The Applicant thus argues that the PHOSITA is thus not motivated to form a double layer particle from the teaching of a granule containing a binder and a single over-coating layer and thus not to form the advantageous product described in claim 1. It is advantageous because it substantially lowers and minimizes the degradation of rumen by-pass quality as explained at page 9-11 of the Application and demonstrated experimentally in Tables 1-5 against particles containing only carnauba wax or hydrogenated vegetable oil layers. As shown in Tables 1-5, this effect is synergic as it is substantially improved (ie. lowered percentage of degradation) compared to a layer consisting of a mix of the carnauba wax and hydrogenated vegetable oil (ref. Control 3 as described at page 24-25 of the Application) in comparable amounts.

The Applicant further argues that Iijima et al. does not teach, nor suggest, the present advantageous solution to the PHOSITA because it also teaches that the binder and coating agent may be the same or different (ref. Col. 7, lines 47-51) and thus interchangeable. This as explained above with the comparison of the results given by Control 3 and the Example compounds according to the invention shows that this teaching of interchangeability according to Iijima et al. points the PHOSITA away from the invention as claimed, further rendering the invention not obvious.

The Applicant thus argues that the main independent product claim is novel and non-obvious.

The Examiner then argues that the limitation to the size of the micronized crystals forming the particles according to claims 2-4 is obvious because it is argued that Iijima et al's teaching of 150 micrometers particle size would have made such a limitation obvious to the PHOSITA. The Applicant argues that claims 2-4 are rendered novel and non-obvious by the lack of teaching or suggestion to said PHOSITA that having the particles double-layered as taught in the present Application is advantageous because it substantially lowers and minimizes the degradation of rumen by-pass quality, as explained at page 9-11 of the Application, and demonstrated experimentally in Tables 1-5 against particles containing only carnauba wax or hydrogenated vegetable oil layers. As shown in Tables 1-5, this effect is synergic as it is substantially improved (ie. lowered percentage of degradation) compared to a layer consisting of a mix of the carnauba wax and hydrogenated vegetable oil (ref. Control 3 as described at page 24-25 of the Application) in comparable amounts.

The Examiner then argues that the limitation of choline chloride percentage in the core according to claims 5-6 is obvious because it is argued that Iijima et al's teaching of choline chloride coated cores, together with routine experimentation by the PHOSITA, would have made the particles according to claims 5-6 obvious, unless otherwise proven. The Applicant argues that claims 5-6 are rendered novel and non-obvious by the lack of teaching or suggestion to said PHOSITA that having the particles double-layered as taught in the present Application is advantageous because it substantially lowers and minimizes the degradation of rumen by-pass quality, as explained at page 9-11 of the Application, and demonstrated experimentally in Tables 1-5 against particles containing only carnauba wax or hydrogenated vegetable oil layers. As shown in Tables 1-5, this effect is synergic as it is substantially improved (ie. lowered percentage of degradation) compared to a layer consisting of a mix of the carnauba wax and hydrogenated vegetable oil (ref. Control 3 as described at page 24-25 of the Application) in comparable amounts.

The Examiner then argues that the limitation of the particles comprising other substances according to claims 7-8, and 39-40, particularly flow modifier, is obvious because it is argued that Iijima et al teaches the use of talc, as a flow modifier, at col.8, lines 32-36. The Applicant argues that claims 7-8 and 39-40 are rendered novel and non-obvious by the lack of teaching or suggestion to said PHOSITA that having the particles double-layered as taught in the present Application is advantageous because it substantially lowers and minimizes the

degradation of rumen by-pass quality, as explained at page 9-11 of the Application, and demonstrated experimentally in Tables 1-5 against particles containing only carnauba wax or hydrogenated vegetable oil layers. As shown in Tables 1-5, this effect is synergic as it is substantially improved (ie. lowered percentage of degradation) compared to a layer consisting of a mix of the carnauba wax and hydrogenated vegetable oil (ref. Control 3 as described at page 24-25 of the Application) in comparable amounts.

The Examiner then argues that the ponderal and composition percentage limitation of the particles comprising other substances according to claims 22-30 is obvious because it is argued that they can be reached from Iijima et al. through routine experimentation, unless a specific advantage is demonstrated. The Applicant argues that claims 22-30 are rendered novel and non-obvious by the lack of teaching or suggestion to said PHOSITA that having the particles double-layered as taught in the present Application is advantageous because it substantially lowers and minimizes the degradation of rumen by-pass quality, as explained at page 9-11 of the Application, and demonstrated experimentally in Tables 1-5 against particles containing only carnauba wax or hydrogenated vegetable oil layers. As shown in Tables 1-5, this effect is synergic as it is substantially improved (ie. lowered percentage of degradation) compared to a layer consisting of a mix of the carnauba wax and hydrogenated vegetable oil (ref. Control 3 as described at page 24-25 of the Application) in comparable amounts.

The Examiner then argues that the inclusion of a rigidity-controlling agent with the carnauba wax in the outer layer according to claims 31-38 is obvious because it is argued that they can be reached from Iijima et al. (col. 3, lines 34-40) through routine experimentation, unless a specific advantage is demonstrated. The Applicant argues that claims 31-38 are rendered novel and non-obvious by the lack of teaching or suggestion to said PHOSITA that having the particles double-layered as taught in the present Application is advantageous because it substantially lowers and minimizes the degradation of rumen by-pass quality, as explained at page 9-11 of the Application, and demonstrated experimentally in Tables 1-5 against particles containing only carnauba wax or hydrogenated vegetable oil layers. As shown in Tables 1-5, this effect is synergic as it is substantially improved (ie. lowered percentage of degradation) compared to a layer consisting of a mix of the carnauba wax and hydrogenated vegetable oil (ref. Control 3 as described at page 24-25 of the Application) in comparable amounts.

The Examiner then argues to claims 46-49 that the limitation of outer coating percentage and inner coating percentage would have been obvious to the PHOSITA because the percentage of the inner and outer coating would be varied during the process of routine optimization of stabilizing choline in the rumen. The Applicant argues that claims 46-49 are rendered novel and non-obvious by the lack of teaching or suggestion to said PHOSITA that having the particles double-layered as taught in the present Application is advantageous because it substantially lowers and minimizes the degradation of rumen by-pass quality, as explained at page 9-11 of the Application, and demonstrated experimentally in Tables 1-5 against particles containing only carnauba wax or hydrogenated vegetable oil layers. As shown in Tables 1-5, this effect is synergic as it is substantially improved (ie. lowered percentage of degradation) compared to a layer consisting of a mix of the carnauba wax and hydrogenated vegetable oil (ref. Control 3 as described at page 24-25 of the Application) in comparable amounts.

The Examiner then argues to claims 50-54 that the limitation of lipids as the hydrophobic substances would have been obvious to the PHOSITA over Iijima et al. The Applicant argues that claims 50-54 are rendered novel and non-obvious by the lack of teaching or suggestion to said PHOSITA that having the particles double-layered as taught in the present Application is advantageous because it substantially lowers and minimizes the degradation of rumen by-pass quality, as explained at page 9-11 of the Application, and demonstrated experimentally in Tables 1-5 against particles containing only carnauba wax or hydrogenated vegetable oil layers. As shown in Tables 1-5, this effect is synergic as it is substantially improved (ie. lowered percentage of degradation) compared to a layer consisting of a mix of the carnauba wax and hydrogenated vegetable oil (ref. Control 3 as described at page 24-25 of the Application) in comparable amounts.

The Examiner then argues to claims 55-56 that the ponderal percentage of the protective coating with respect to the whole particles would have been obvious to the PHOSITA during the process of routine optimization of stabilizing choline chloride in the rumen. The Applicant argues that claims 55-56 are rendered novel and non-obvious by the lack of teaching or suggestion to said PHOSITA that having the particles double-layered as taught in the present Application is advantageous because it substantially lowers and minimizes the degradation of rumen by-pass quality, as explained at page 9-11 of the Application, and demonstrated experimentally in Tables 1-5 against particles containing only carnauba wax or hydrogenated vegetable oil layers. As shown in Tables 1-5, this effect is synergic as it is substantially improved (ie. lowered percentage of degradation) compared to a layer

consisting of a mix of the carnauba wax and hydrogenated vegetable oil (ref. Control 3 as described at page 24-25 of the Application) in comparable amounts.

At point 6, the Examiner argues that claims 9-14 and 57-59 are obvious by combining Iijima et al. and Richardson et al. Richardson et al. teaches, at col. 3 lines 41-50, choline chloride encapsulated with a lipid coating and combined with the moist composition, which could be ruminant feed. Both carnauba wax and hydrogenated vegetable oils are indicated as possible lipid coating materials. The Examiner cites col. 10, lines 11-13 to show that the PHOSITA would have been motivated to combine the teaching of using silicate as flow modifiers with the description of the granules of Iijima et al. to reach the present invention as described in claims 9-14.

The Applicant argues that present claims 9-14 are rendered novel and non-obvious by the lack of teaching or suggestion, in both Iijima et al. and Richardson et al., that having the particles double-layered, as taught in the present Application, is advantageous because it substantially lowers and minimizes the degradation of rumen by-pass quality, as explained at page 9-11 of the Application, and demonstrated experimentally in Tables 1-5 against particles containing only carnauba wax or hydrogenated vegetable oil layers. As shown in Tables 1-5, this effect is synergic as it is substantially improved (ie. lowered percentage of degradation) compared to a layer consisting of a mix of the carnauba wax and hydrogenated vegetable oil (ref. Control 3 as described at page 24-25 of the Application) in comparable amounts.

The Applicant argues the same reasoning applies with regards to the limitation of the composition in feed pellet, premix for feed with the composition, and mash feed featured in Richardson et al. as taught in col.3, lines 54-55.

At point 7, the Examiner argues that claims 15-19 and 41-42 are obvious by combining Iijima et al. in view of Brommelsiek et al. Brommelsiek et al. teaches binders acting as moisture barriers, specifically calcium stearates. The Examiner combines said teaching of Brommelsiek with Iijima et al to arrive to the invention as described in claims 15-19 and 41-42.

The Applicant argues that these claims are rendered novel and non-obvious by the lack of teaching or suggestion, in both Iijima et al. and Brommelsiek et al., that having the particles double-layered, as taught in the present Application, is advantageous because it

substantially lowers and minimizes the degradation of rumen by-pass quality, as explained at page 9-11 of the Application, and demonstrated experimentally in Tables 1-5 against particles containing only carnauba wax or hydrogenated vegetable oil layers. As shown in Tables 1-5, this effect is synergic as it is substantially improved (ie. lowered percentage of degradation) compared to a layer consisting of a mix of the carnauba wax and hydrogenated vegetable oil (ref. Control 3 as described at page 24-25 of the Application) in comparable amounts.

Furthermore, the Applicant would like to point out how Brommelsiek et al. teaches the use of binders in the same way as the Application, whereas Iijima et al. teaches the use of one or two of the materials mentioned above with the same function of binder as calcium stearate. Thus the Applicant argues there is a strong inconsistency in combining the teaching of Brommelsiek et al. with Iijima et al.

At point 8, the Examiner combines all three documents to argue that claims 20-21 and 43-45 are obvious. As the Applicant has argued above, there is nothing in the three documents to suggest the advantages brought by the double layered particle as taught in the Application, thus he argues that the combination thereof does not render the invention obvious.

For all these reasons, it is apparent that the claims as now presented clearly define over the prior art. Accordingly, a Notice of Allowance is now in order and is respectfully requested.

If any additional fees are required by this communication, please charge such fees to our Deposit Account No. 16-0820, Order No. BUG5-36500.

Respectfully submitted,

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